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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,740	09/03/2004	Marcus Geese	220401-1020	3579

7590 04/20/2007

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EXAMINER	
HIRIYANNA, KELAGINAMANE T	
ART UNIT	PAPER NUMBER
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,740	GEESE ET AL.	
	Examiner	Art Unit	
	Kelaginamane T. Hiriyanna	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-15 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-15 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/06/05*..
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction of invention

Applicant's election without traverse of restriction requirement in the reply filed on March 08, 2007 is acknowledged. Applicant elects without traverse the invention Group-III claims 1, 11-15 and 27 drawn to a pharmaceutical composition comprising SCAD polypeptide, variants or fragments said peptide and to an 'effector' of said polypeptide and to a kit comprising an antibody.

Claims 2-10 and 16-26 are cancelled.

Claims 1, 11-15 and 27 are pending and presently under examination.

Priority

Priority date for elected invention is applied under 35 USC§119(a-d) for the Foreign Application No.(EPO) 02 005141.3 filed on 03/07/2002.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-15 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14-15 provide for the use of 'SCAD gene family of peptides', but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 14-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35

U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

"The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

Claims *1-20* are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of invention as claimed encompasses to a pharmaceutical composition comprising any and/or all short-chain dehydrogenases (SCAD) gene family polypeptides and/or their fragments and/or their variants of said SCAD polypeptides and any and/or all antibodies to said polypeptides.

At the best the specification teaches a composition of mouse (DG-21-1 and DG-21-2) and human homolog of Drosophila CG3842 polypeptide, a recombinant polypeptide expression of said homolog and an expression profiling of said homologs that indicates that they may be involved in the regulation of energy metabolism in mammalian cells. Applicant further broadly discloses other art information regarding SCAD gene family polypeptides. Such broad guidance would not constitute the specific direction and guidance the artisan would require to reasonably predict that any SCAD polypeptide or its variants can be used, that any disease or disorder can be treated with said compositions.

The application does not disclose sufficient number of examples of compositions comprising broadly claimed variants and fragments of said polypeptide that are similar to structural and functional properties of said polypeptide encoded by human homolog of

Drosophila CG3842. Thus the number and type of examples provided does not commensurate with the scope and breadth of instant claims.

Applicant is referred to the guidelines for ***Written Description Requirement*** published January 5, 2001 in the Federal Register, Vol.66, No.4, pp.1099-1110 (see <http://www.uspto.gov>). The disclosure of a single species is rarely, if ever, sufficient to describe a broad genus, particularly when the specification fails to describe the features of that genus, even in passing. (See In re Shokal 113USPQ283(CCPA1957); Purdue Pharma L. P. vs Faulding Inc. 56 USPQ2nd 1481 (CAFC 2000). In analyzing whether the written description requirement is met for the genus claim, it is first determined whether a representative number of SCAD peptide species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. conserved motifs or domains).

Since the specification fails to disclose other claimed compositions that contained sufficient number of examples of polypeptide variants and/or fragments, it is not possible to envision the broadly claimed compositions providing the same results as the polypeptide of CG3842 human homolog itself. One cannot describe what one has not conceived. (See Fiddes v. Baird, 30 USP2d 1481 at 1483). Therefore, the lack of disclosure in the specification is not deemed sufficient to reasonably convey to one skilled in the art that the applicants were in possessions of the huge genera recited in the claims at the time the application was filed. Furthermore the possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with *sufficient relevant identifying characteristics* (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *See, e.g., Pfaff v. WellsElectronics, Inc., 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; Amgen, Inc. v. Chugai Pharmaceutical, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).* In the instant case the compositions as claimed has been defined only by a statement of function that broadly encompasses all SCAD gene family of peptides, their variants and fragments which conveyed no

distinguishing information about the identity of the broadly claimed species. Accordingly one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of a single member of this genus would not be representative of claimed genus of compounds and is insufficient to support the claim in its present scope. At the best the specification provides the enabled description of a compositions of a mouse (DG-21-1 and DG-21-2) and a human homolog of Drosophila CG3842 polypeptide.

Claims 1, 11-15 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a compositions of a mouse (DG-21-1 and DG-21-2) and a human homolog of Drosophila CG3842 polypeptide and an antibody to said polypeptide, is not enable pharmaceutical compositions any SCAD polypeptide, or its variants or fragments, is not enabled for treating any disease or disorder using said polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Since the specification fails to disclose a any SCAD protein or polypeptide fragments, and variants used in the treatment of any diseases as claimed, it is unclear how one skilled in the art use the invention as claimed (supra). The applicant's disclosure does not enable one skilled in the art to practice the invention as claimed without further undue amount of experimentation, which requires the identification and characterization of any and/or all SCAD proteins, their fragments and variants derived from any and all organisms and further screening them for their therapeutic potential to treat or diagnose an enormous number of diseases or disorders as claimed. At issue, under the enablement requirement of 35 U.S.C. 1 12, first paragraph is whether, given the Wands-factors, the experimentation was undue or unreasonable under the circumstances. "Experimentation must not require ingenuity beyond that to be expected of one of ordinary skill in the art." See Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1970).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11-15 and 27.are rejected under 35 USC 102 (b) as being anticipated by Lal et al., (US Patent No.: 6057,140).

The above claims are directed to a pharmaceutical composition comprising short chain dehydrogenase (SCAD) gene family polypeptides and fragments and variants of said SCAD polypeptides and use of said composition for diagnostic, treatment, alleviation or prevention of metabolic disorders and diseases including metabolic syndrome, diabetes, coronary heart disease etc.

Regarding claims 1, 11-15 and 27. Lal teaches SCAD gene family polypeptides, fragments and variants and their composition (Abstract, col. 11-12, col.20) and the therapeutic use of these peptide compositions in treating various disorders associated with the abnormal expression of human SCAD family of molecules (HSFM) including various metabolic disorders (fatty acid and steroid metabolism) (co.20, lines 16-67 bridging col.21-22). Lal further discloses antibodies to SCADs and immunological methods of diagnosis and treatment (col.18, Lines 49-64). The cited art thus anticipates the invention as claimed.

Claims 1, 11-15 and 27.are rejected under 35 USC 102 (b) as being anticipated by Mao et al., (WO 01/74999).

The above claims are directed to a pharmaceutical composition comprising short chain dehydrogenase (SCAD) gene family polypeptides and fragments and variants of said SCAD polypeptides and use of said composition for diagnostic, treatment, alleviation or prevention of metabolic disorders and diseases including metabolic syndrome, diabetes, coronary heart disease etc.

Regarding claims 1, 11-15 and 27. Mao teaches a novel polypeptide-short chain dhydrogenase encoding polynucleotide and polypeptides derivatives of same and further discloses compositions and methods SCAD gene family polypeptides, and the use of said polypeptide for the treatment of various kinds of diseases including metabolic block of substance and energy (metabolic diseases, metabolic syndrome etc). Further and antagonist of the polypeptide (antibody, effector) and therapeutic use of the same is disclosed. The cited art thus anticipates the invention as.claimed.

Conclusion:

No claim allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Kelaginamane Hiriyanna* whose telephone number is **(571) 272-3307**. The examiner can normally be reached Monday through Friday from 9 AM-5PM. Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst *William N. Phillips* whose telephone number is ***571 272-0548.*** If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Joseph Woitach*, may be reached at **(571) 272-0739.** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). When calling please have your application serial number or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. For all other customer support, please call the USPTO call center (UCC) at (800) 786-9199.

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